DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockvilie MD 20857

SEP 6 1999

3312 '99 SEP 17 19 30

The Honorable Mitch McConnell
United States Senate
Washington, D.C. 20510-1702

Dear Senator McConnell:

Thank you for your letter of August 19, 1999, on behalf of several of your constituents, regarding dietary supplements containing ephedrine alkaloids. Ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. The ephedrine alkaloids in dietary supplements are naturally occurring stimulants and usually are derived from one of several species of herbs of the genus Ephedra, sometimes called Ma huang or Chinese Ephedra.

On June 4, 1997, the Food and Drug Administration (FDA or the Agency) published a proposed rule in the Federal Register regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. In the proposed rule, the Agency is proposing:

- to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids;

- to require that the label of dietary supplements that contain ephedrine alkaloids state, "Do not use this product for more than 7 days";

- to prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids;

95N-0304

LETT4/ANS

- to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building);

- to require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that, "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and

- to require specific warning statements to appear on product labels.

The proposal also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements.

FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products, which contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors, and headaches, to seizures, strokes, and death. As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products which contained, or were suspected of containing, ephedrine alkaloids. The adverse events reports showed consistent patterns of illness and injury among otherwise healthy individuals and those with underlying diseases or conditions. FDA continues to receive additional reports of adverse events associated with the use of these products.

The proposed measures were developed based on FDA's review of its adverse event reports, the scientific literature, and public comments reviewed by the Agency, including comments generated by an October 1995 advisory working group public meeting and an August 1996 public meeting of FDA's Food Advisory-Committee. These experts suggested a number of steps the Agency might take to reduce injuries associated with the

use of dietary supplements containing ephedrine alkaloids. If implemented, the proposed rule will reduce the risk of adverse events for consumers who use these products.

There was an initial 75-day comment period on the proposed rule. On September 18, 1997 (62 FR 48968), that comment period was reopened for an additional 75 days until December 2, 1997. Your comments have been forwarded to the Administrative Docket for this issue. While the Agency is under no legal obligation to consider comments received after the comment period has closed, we do try to accommodate all comments as time and resources permit. Currently, the Agency is considering all comments, data, and other information it has received in developing a final rule.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

for Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket #95N-0304)

MITCH McCONNELL
KENTUCKY

361-A RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1702
(202) 224-2541

United States Senate

COMMITTEES
RULES AND ADMINISTRATION CHAIRMAN
AGRICULTURE
APPROPRIATIONS
CHAIRMAN, SUBCOMMITTEE ON
FOREIGN OPERATIONS

August 19, 1999

Dr. Jane Henney
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

Several Constituents recent-ly shared with me concerns regarding dietary supplements containing naturally occuring ephedrine alkaloids.

I would greatly appreciate your review of these concerns. Please find enclosed a sample of this correspondence for your reference.

Thank you for your consideration of this matter. I look forward to your reply.

Sincerely,

MITCH McCONNELL
UNITED STATES SENATOR

MM/scb

Enclosure

No. 99-5572

FEDERAL BUILDING
241 E. MAIN STREET
ROOM 102
BOWLING GREEN, KY 42101
(502) 781-1673

1885 DIXIE HIGHWAY
SUITE 345
FORT WRIGHT, KY 41011
(606) 578-0188

771 CORPORATE DRIVE
SUITE 530
LEXINGTON, KY 40503
606 224-8286

301 SOUTH MAIN STREET
LONDON, KY 40741
(606) 864-2026

601 WEST BROADWAY
SUITE 630
LOUISVILLE, KY 40202
(502) 582-6304

IRVIN COBB BUILDING
602 BROADWAY
PADUCAH, KY 42001
(502) 442-4554

Dear Senator Mitch McConnell

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts *all* dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the kvek of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid. Cold and allergy products. which can be purchased at any grocery store without a prescription, contain over three *times* the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and let my voice be heard!

Sincerely (signature) Teresa D Fincken

Name Teresa D. FINCKEN

Address 335 [illegible] Falls Dr

City Er[illegible] County Kenton

State KY Zip Code 41018-2651